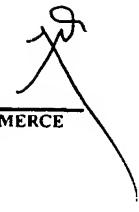




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,967	08/01/2003	Alexander Hillisch	GULDE-0002	2520
23599	7590	04/12/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			BADIO, BARBARA P	
		ART UNIT	PAPER NUMBER	
			1617	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/631,967	HILLISCH ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-9, 11-13 and 17 is/are allowed.
- 6) Claim(s) 10 and 14 is/are rejected.
- 7) Claim(s) 15 and 16 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 101***

2. **The rejection of claims 8-16 under 35 USC 101 is withdrawn.**

***Claim Objections***

3. **The objection to claims 3 and 6 under 37 CFR 1.75(c) is withdrawn.**

***Claim Rejections - 35 USC § 112***

4. **The rejection of claim 14 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.**

Applicant argues one of ordinary skill in the art knows the meaning of a prodrug. According to applicant, sulfamates are well known prodrugs and, thus, applicants had possession of the claimed invention. Applicant's argument was considered but not persuasive for the following reasons.

The issue is not whether one of ordinary skill in the art knows the general meaning of the word "prodrug" and its use. The issue is whether the present specification defines what applicant intends by the use of the term "prodrug".

The examiner notes applicant's argument that "sulfamates" are known to be prodrugs of steroids. However, the art identifies different moieties as prodrugs and it varies from paper to paper.

Even if one agrees that sulfamates are known to be prodrugs, the present specification does not identify said sulfamates as prodrugs nor does it define what applicant intends as "prodrug" (see page 9, 3<sup>rd</sup> paragraph of the present specification). Therefore, the skilled artisan in the art at the time of the present invention would not know what is encompassed by the use of the term "prodrug" in the present invention. The present specification lacks description of "prodrug" in full, clear, concise and exact terms as required by 35 USC 112, first paragraph.

For these reasons and those given in the previous Office Action, the rejection of claim 14 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

**5. The rejection of claims 6, 8-13, 15 and 16 under 35 USC 112, second paragraph is withdrawn.**

**6. The rejection of claim 14 under 35 USC 112, second paragraph is maintained.**

Applicant argues that the term is not indefinite because of its meaning is well understood to one of ordinary skill in the art. Applicant's argument was considered but not persuasive for the following reason.

The general meaning of the term “prodrug” is not the issue because as stated by applicant the term is understood by one of ordinary skill in the art. However, what applicant intends by the use of the term is indefinite because the present specification lacks definition and examples of what is encompassed by said term.

For this reason and those given in the previous Office Action, the rejection of claim 14 under 35 USC 112, second paragraph is maintained.

7. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claim creates confusion as to the claimed invention. The claim recites a method for “the production of pharmaceutical agents for treating a dysmenorrhea, comprising administering to a host in need thereof a compound of claim 1”. It is unclear how one can produce pharmaceutical agents that would treat dysmenorrhea by the administration of the claimed compound.

#### ***Claim Rejections - 35 USC § 102***

8. **The rejection of claims 1, 3-5 and 7-13 under 35 USC 102(b) over Schubert et al. (WO 99/45023, see US 6,365,582 for English translation) is withdrawn.**

***Claim Rejections - 35 USC § 103***

9. The rejection of claims 1 and 3-13 under 35 USC 103(a) over Schubert et al. (WO 99/45023, see US 6,365,582 for English translation) is withdrawn.

10. The rejection of claims 1 and 3-13 under 35 USC 103(a) over Schubert et al. (US 5,693,628) is withdrawn.

***Allowable Subject Matter***

11. Claims 1-9, 11-13 and 17 are allowed.

12. Claims 15 and 16 are objected to as depending on a rejected base claim.

***Other Matters***

13. The examiner notes a call was made to applicant on March 14, 2006 but did not result in the resolution of the above rejections.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

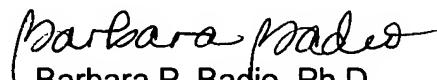
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
April 6, 2006